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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/885,568 | 06/20/2001 | John Jianhua Chen | S63.2-9515 | 8081 |

490 7590 02/15/2005

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| EXAMINER | |
|---|---|
| HON, SOW FUN | |
| ART UNIT | PAPER NUMBER |
| 1772 | |

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/885,568 | Applicant(s) CHEN ET AL. | |
|---|---|---|---|
| | Examiner Sow-Fun Hon | Art Unit 1772 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14,16,18-21,24 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16,18-20,24-25* is/are rejected.

7)☒ Claim(s) *21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/29/04*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/08/04 has been entered.

### *Withdrawn Rejections*

2. The U.S.C. 112, 2nd paragraph and 103(a) rejections have been withdrawn due to Applicant's amendment dated 10/08/04.

### *New Rejections*

### *Claim Rejections - 35 USC § 103*

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-7, 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al. (WO 95/18647) in view of Zdrahala (US 5,248,305), as evidenced by Bland et al. (US 5,427,842).

Regarding claim 1, Rau has a balloon for a medical device (catheter) (column 1, lines 10-15) comprising a plurality of fibers to provide reinforcement (column 14, lines 25-30). The reinforcing fiber may comprise LCP (liquid crystal polymers) (column 15, lines 1-5). The fibers

(filaments) are aligned parallel along the structure (column 15, lines 5-10) which means that the fibers are oriented parallel to the longitudinal axis of the balloon. This is a specific example of the fibers being distributed in a selected direction relative to the balloon axis. The liquid crystal polymer fiber has greater tensile strength than the thermoplastic polymer matrix, as evidenced by Zdrahala.

Zdrahala teaches that the desired high tensile strength is provided by liquid crystal polymer reinforcement of thermoplastics (column 3, lines 10-25).

Rau fails to teach that the matrix material of the balloon is a block copolymer. However, because Rau discloses prior art which teaches the use of ethylene butylene styrene block copolymer as a matrix material for a balloon (column 1, lines 15-20), it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have used ethylene butylene styrene block copolymer instead of thermoplastic polyimide (column 2, lines 15-20) as the matrix material of Rau, in order to obtain a balloon with the alternate physical properties provided by a block copolymer.

Regarding claim 3, Rau teaches that the shaft may be composed of a blend of polymer (polyimide) and liquid crystal (column 16, lines 20-25), and that when the balloon is integral with the shaft (column 14, lines 10-15), the matrix polymer is thermoplastic polymer (polyimide). Thus the balloon is of the same composition as the shaft when it is integral with the shaft, and is composed of a blend of thermoplastic polymer and liquid crystal. As a blend, the liquid crystal polymer fiber reinforcement cores are coextruded with the matrix thermoplastic polymer material (column 14, lines 10-20).

Regarding claims 4-5, Rau teaches that the liquid crystal polymers are rigid, rod-like (column 16, lines 25-30). The liquid crystal rods thus constitute cores of polymeric material which have a bulk elongation of less than 150 % (claim 4). The liquid crystal rods are aligned parallel along the structure (column 15, lines 5-10) which means that they are oriented parallel to the longitudinal axis of the balloon. Being rigid, the liquid crystal core polymeric material has a bulk elongation less than the matrix material when oriented in the direction of the longitudinal axis (claim 5).

Regarding claim 6, Rau teaches that the balloon may comprise a plurality of laminate layers (column 10, lines 10-20), at least one of which comprises said polymer matrix material and said fibers (reinforcing components) (column 14, lines 25-30).

Regarding claim 7, Rau teaches that selectively altering the number, arrangement and thickness of the balloon in a variety of configurations provides the opportunity of tailoring the compliance characteristics of the balloon (column 10, lines 20-25).

Regarding claim 12, Rau teaches that the fibers (filaments) are aligned parallel along the structure (column 15, lines 5-10) which means that the fibers are oriented parallel to the longitudinal axis of the balloon.

Regarding claims 2, 9, Rau fails to teach that the liquid crystal polymer fibers are distributed in the matrix material helically relative to the balloon axis.

Zdrahala teaches a catheter tubing which exhibits stiffness in the longitudinal direction as well as rotational stiffness and both may be varied along the length of the tubing (column 1, lines 55-70 and column 2, lines 1-5). One embodiment teaches that the liquid crystal fibers are distributed in the matrix material helically relative to the balloon axis (separate phase of liquid

crystal plastic forms helical extending, separate fibrils within the extruded tubing with the fibers (fibrils) being dispersed in the structural plastic matrix) (column 5, lines 1-15). Zdrahala teaches that the helical fibers provide rotational stiffness to the tube (column 8, lines 15-20). Zdrahala thus demonstrates that it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have distributed the liquid crystal polymer fibers in the matrix material helically relative to the balloon axis of Rau, in order to provide some rotational stiffness to control the radial expansion of the balloon.

Regarding claim 10, Rau teaches that as a blend, the liquid crystal polymer fiber reinforcement cores are coextruded with the matrix thermoplastic polymer material (column 14, lines 10-20).

Regarding claims 11, 13, Rau fails to teach that the fibers have a diameter of from 0.01 to about 10 microns.

Zdrahala teaches that the fibers (fibrils) exhibit an aspect ratio of about 10 to 300, the aspect ratio being defined by the length of the fiber divided by its diameter (column 5, lines 15-25). The walls of the balloon catheters have dimensions smaller than the blood vessels which contain them, on the order of microns. Thus the fiber diameter can be no larger than the walls of the balloon catheters, and can only be on the order of microns. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided fiber dimensions for the balloon of Rau, which conform to balloon catheter wall dimensions suitable for the dimensions of the blood vessel of interest, wherein the claimed range of the LCP (liquid crystal polymer) fiber diameter of from 0.01 to about 10 microns is obtained to provide the desired aspect ratio taught by Zdrahala.

5. Claims 1, 7-8, 14, 16, 18-21, 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al. in view of Bland, as evidenced by Zdrahala.

Regarding claim 1, Rau has a balloon for a medical device (catheter) (column 1, lines 10-15) comprising a plurality of fibers to provide reinforcement (column 14, lines 25-30). The reinforcing fiber may comprise LCP (liquid crystal polymers) (column 15, lines 1-5). The fibers (filaments) are aligned parallel along the structure (column 15, lines 5-10) which means that the fibers are oriented parallel to the longitudinal axis of the balloon. This is a specific example of the fibers being distributed in a selected direction relative to the balloon axis. The liquid crystal polymer fiber has greater tensile strength than the thermoplastic polymer matrix, as evidenced by Zdrahala.

Zdrahala teaches that the desired high tensile strength is provided by liquid crystal polymer reinforcement of thermoplastics (column 3, lines 10-25).

Rau fails to teach that a block copolymer is used in the matrix material of the balloon. However, Rau discloses prior art which teaches that ethylene butylene styrene block copolymer is used for the matrix material of the balloon (column 1, lines 15-20). Therefore, because Rau discloses prior art which teaches the use of a block copolymer for the matrix material of the balloon, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have used ethylene butylene styrene block copolymer instead of thermoplastic polyimide as the matrix material of the balloon of Rau (column 2, lines 15-20), in order to obtain a balloon with the alternate physical properties provided by a block copolymer.

Regarding claim 6, Rau teaches that the balloon may comprise a plurality of laminate layers (column 10, lines 10-20), at least one of which is composed of a polymer matrix material and LCP (liquid crystal polymer) (column 14, lines 25-30).

Regarding claims 7, 8, 14, Rau teaches that the balloon may comprise a plurality of laminate layers (column 10, lines 10-20), at least one of which is composed of a polymer matrix material and LCP (liquid crystal polymer) (column 14, lines 25-30). One embodiment has inner and outer layers of polymer matrix material (thermoplastic polyimide) surrounding an intermediate layer of the blend of polymer matrix material and LCP (column 17, lines 10-15), which meets the recitation in claim 7 of laminate layers comprising an alternating series of fiber-containing and fiber-free layers. Selectively altering the number and arrangement of these layers provides the opportunity of tailoring the compliance characteristics of the balloon (column 10, lines 20-25).

Rau fails to teach at least 7 layers in an alternating series of fiber-containing and fiber-free layers (claim 8); or 7 to 50 layers in an alternating series of LCP-containing and LCP-free layers (claim 14).

Bland teaches that angioplasty balloons require stiff tear-resistant films since they cannot tear during use, and must inflate to a controlled size and not stretch to a larger size (column 1, lines 45-50). Bland teaches a tear-resistant multilayer film comprising alternating layers of relatively stiff and ductile polymeric materials (column 1, lines 10-15) (claim 7). The tear resistant film comprises more than 5 layers and which overlaps the claimed range of at least 7 laminate layers (column 3, lines 30-40) (claim 8), and from more than 5 layers to 35 layers, up to

61 layers (column 6, lines 50-60), which overlaps the claimed range of from 7 to 50 total polymer layers (claim 14).

Rau teaches that selectively altering the number and arrangement of the layers of LCP-reinforced layers (layers B) with LCP-free layers (layers A) provides the opportunity of tailoring the compliance characteristics of the balloon (column 10, lines 20-25). The LCP fiber-reinforced layers of Rau are relatively stiff due to the rigidity of the liquid crystal polymer reinforcement (column 16, lines 20-25).

Bland teaches that angioplasty balloons require stiff tear-resistant films since they cannot tear during use, and must inflate to a controlled size and should not stretch to a larger size (column 1, lines 45-50). Therefore Bland demonstrates that it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided the balloon of Rau, with laminate layers comprising from 7 to 50 layers of an alternating series of LCP fiber-containing and LCP fiber-free layers, in order to obtain an angioplasty balloon with improved tear resistance and controlled inflation dimension.

Regarding claim 16, Rau teaches the balloon may comprise a plurality of laminate layers (column 10, lines 10-20), at least one of which is composed of a polymer matrix material and LCP (liquid crystal polymer) (column 14, lines 25-30), wherein one embodiment has inner and outer layers of polymer matrix material (thermoplastic polyimide) surrounding an intermediate layer of the blend of polymer matrix material and LCP (column 17, lines 10-15). Hence the single polymer material and the matrix polymer material are the same.

Regarding claims 18-19, Rau shows in Fig. 16, inner and outer layers of thermoplastic polymer surrounding an intermediate layer comprising a blend (column 5, lines 15-20). The

single polymer layers (A) are thicker than the intermediate blend layer (B). Rau teaches that selectively altering the thickness, number and arrangement of these layers provides the opportunity of tailoring the compliance characteristics of the balloon (column 10, lines 20-25). Therefore, because Rau teaches that selectively altering the thickness and number of the arrangements provides tailoring of the compliance characteristics of the balloon, it would hve been obvious to one of ordinary skill in the art at the time the invention was made, to have provided the claimed ratio A/B of the total thickness of the two types of layers (A) and (B) respectively, of from about 5 to about 15 (claim 18), and of from about 8 to about 10 (claim 19), in order to obtain the desired compliance characteristics for the balloon of Rau.

Regarding claim 20, Rau fails to teach that the LCP polymer is present in the blend in an amount of from about 5 to about 25 % by weight.

Zdrahala teaches that the composition of a catheter tubing can contain from 5 to 35 weight percent of the LCP (liquid crystal polymer) (column 4, lines 15-35). The range is within the claimed range of from about 5 to about 25 % by weight.

Therefore Zdrahala demonstrates that it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided the claimed range of from about 5 to about 25 % by weight of LCP in the LCP blend of Rau, in order to obtain a balloon catheter with the desired reinforcement.

Regarding claim 21, Rau teaches that the fibers are aligned parallel along the structure (column 15, lines 5-10) which means that the fibers are oriented parallel to the longitudinal axis of the balloon.

Regarding claims 24-25, Rau fails to teach that the block copolymer of layer (A) is compliant or semi-compliant and that said block copolymer of layer (B) is compliant or semi-compliant.

Bland teaches that the ductile polymer may be a polyamide (column 4, lines 45-55) copolymerized with a long chain polyethylene glycol (column 9, lines 1-5), a polyether, forming a block copolymer comprising polyamide blocks and polyether blocks. Applicant's specification teaches that block copolymer comprising polyamide blocks and polyether blocks belongs to the group of "compliant" or "semi-compliant" polymer (page 10, lines 28-31). The term "ductile" of Bland thus overlaps the terms "compliant" and "semi-compliant" of Applicant.

Rau teaches that selectively altering the number and arrangement of the layers of LCP-reinforced layers with LCP-free layers provides the opportunity of tailoring the compliance characteristics of the balloon (column 10, lines 20-25).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have used the "compliant" or "semi-compliant" polyamide-polyether block copolymer of Bland as the matrix material of Rau, in order to obtain a balloon with the desired compliance characteristics, as taught by Rau.

***Response to Arguments***

6. Applicant's arguments with respect to claims 1-14, 16, 18-21 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Hon

Sow-Fun Hon

01/07/05